Amendments to the Claims

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (currently amended) A pharmaceutical dosage form comprising ~~the active substance~~ N-(2-(2-phthalimidoethoxy)-acetyl)-L-alanyl-D-glutamic acid.

2. (currently amended) The pharmaceutical dosage form according to claim 1 wherein the dosage form is suitable for controlled [[and /]] or targeted delivery of ~~the active substance~~ N-(2-(2-phthalimidoethoxy)-acetyl)-L-alanyl-D-glutamic acid to the distal portions of the gastrointestinal tract of humans and animals.

3. (currently amended) The pharmaceutical dosage form according to claim 2 wherein the distal portions of the gastrointestinal tract are selected from the group consisting of the ileum, the ceacum and the colon.

4. (currently amended) The pharmaceutical dosage form according to ~~any one of claims from 1 to 3~~claim 1 wherein the dosage form is administered to humans or animals in the amount from about 10 mg to about 1000 mg of the active substance according to claim 1 in a single dose or more divided doses.

5. (currently amended) The pharmaceutical dosage form according to ~~any one of claims 1 to~~ [[4]]claim 1 wherein the dosage form comprises a core and an inner coat.

6. (currently amended) The pharmaceutical dosage form according to claim 5 wherein the core comprises ~~the active substance~~ N-(2-(2-phthalimidoethoxy)-acetyl)-L-alanyl-D-glutamic acid and a polysaccharide.

7. (currently amended) The pharmaceutical dosage form according to claim 6 wherein the polysaccharide is selected from the group consisting of pectin or alginate, either in the form of acid or in the form of metal salt, galactomannans, covalently crosslinked dextran, amylose, xanthans, carrageenan, their respective salts with the same specific degradability, [[and]] starch [[or]] and combinations thereof~~of the said polysaccharides or their salts with the same specific degradability~~.

8. (original) The pharmaceutical dosage form according to claim 7 wherein the polysaccharide is selected from the group consisting of pectin and calcium pectinate.

9. (original) The pharmaceutical dosage form according to claim 6 wherein the core is a solid dispersion of the active substance in the calcium pectinate, forming a calcium pectinate matrix.

10. (original) The pharmaceutical dosage form according to claim 6 wherein the core further comprises a glidant selected from the group consisting of magnesium stearate, calcium stearate and aerosil.

11. (original) The pharmaceutical dosage form according to claim 5 wherein the inner coat prevents the release of the active substance in the proximal portions of the small intestine.

12. (currently amended) The pharmaceutical dosage form according to claim 11 wherein the inner coat comprises a polymer selected from the group consisting of methacrylate ester copolymers, a mixture of polyvinyl acetate and polyvinylpyrrolidone and[[/or]] combinations thereof.

13. (currently amended) The pharmaceutical dosage form according to claim 12 wherein the ~~selected combination of~~ polymer[[s]] is a combination of copolymers of acrylic and methacrylic acid esters [[with]] having a low content of quartenary ammonium groups.

14. (currently amended) The pharmaceutical dosage form according to claim 5 wherein the dosage form further comprises an outer coat which is insoluble in ~~an acidic environment~~ at a pH below 5 and prevents release of the N-(2-(2-phthalimidoethoxy)-acetyl)-L-alanyl-D-glutamic acid~~active substance~~ in [[the]] an acidic medium of [[the]] a stomach of an animal or human.

15. (currently amended) The pharmaceutical dosage form according to claim 14 wherein the outer coat comprises an acidoresistant polymer selected from the group consisting of: derivatives of methacrylic acid copolymer, hydroxypropylmethyl cellulose phthalate, hydroxyethylcellulose phthalate, cellulose acetate phthalate, polyvinyl acetyl phthalate, hydroxypropylmethylcellulose acetate succinate [[or]]and combinations thereof.

16. (currently amended) The pharmaceutical dosage form according to claim 15 wherein the acidoresistant polymer is an anionic copolymer ~~based on~~comprising methacrylic acid and ethyl acrylate.

17. (currently amended) The pharmaceutical dosage forms according to claim[[s 12 and]] 15 wherein the inner coat or outer coat further comprises a glidant selected from the group consisting of talc, kaolin and glycerol monostearate.

18. (original) The pharmaceutical dosage form according to claim 17 wherein the glidant is talc.

19. (currently amended) The pharmaceutical dosage forms according the claim[[s 12 and]] 15 wherein the inner coat or outer coat[[s]] further comprise a plasticizer selected from the group consisting of triethyl citrate, tributyl citrate, acetyltriethyl citrate, acetyltributyl citrate, diethyl phthalate, dibutyl phthalate, dibutyl sebacate, glyceryl triacetate, triacetin, polyethylene glycol 6000 and polyoxyethylene (20) sorbitan monooleate.

20. (original) The pharmaceutical dosage form according to claim 19 wherein the plasticizer is triethyl citrate.

21. (currently amended) A pharmaceutical dosage form comprising:

a core [[-]]comprising a calcium pectinate matrix in which ~~the active substance~~ N-(2-(2-phthalimidoethoxy)-acetyl)-L-alanyl-D-glutamic acid is dispersed, the core further comprising magnesium stearate[[, and]];

an inner coat [[-]] comprising polymers Eudragit RS and Eudragit RL, talc and triethyl citrate[[,]]; and

an outer coat [[-]] comprising polymer Eudragit L-55, talc and triethyl citrate.

22. (currently amended) A pharmaceutical dosage form comprising:

a core [[-]] comprising a calcium pectinate matrix in which an active substance is dispersed, the core further comprising magnesium stearate[[, and]];

an inner coat [[-]] comprising polymers Eudragit RS and Eudragit RL, talc and triethyl citrate[[,]]; and

an outer coat [[-]] comprising polymer Eudragit L-55, talc and triethyl citrate.

23. (currently amended) The pharmaceutical dosage form according to claim 22 wherein the active substance is ~~selected from the group consisting of any active substances that need the~~ suitable for controlled [[and/]]or targeted delivery to the distal portions of the gastrointestinal tract of humans or animals.

24. (currently amended) The pharmaceutical dosage form according to claim 23 wherein the distal portions ~~of the gastrointestinal tract~~ are selected from the group consisting of the ileum, the caecum and the colon.

25. (currently amended) The pharmaceutical dosage form according to ~~any of claims from 1 to 24~~claim 1 wherein the dosage form ~~may be in a form of~~is a microcapsule, a coated microparticle, a coated microsphere, a coated granule, a coated pellet, a tablet or a capsule.

26. (currently amended) The pharmaceutical dosage form according to claim 25 wherein the dosage form is ~~in a form of~~ a microcapsule.

27. (original) The pharmaceutical dosage form according to claim 26 wherein the microcapsules are further incorporated into an inert tablet matrix or an inert capsule.

28. (currently amended) The pharmaceutical dosage form according to claim 5 wherein the dosage form is ~~in a form of~~ a microcapsule which is embedded into:

~~either into~~a gastroresistant tablet matrix forming a tablet[[, or]];

[[into]] an inert tablet matrix which is subsequently coated with a ~~coat from a~~ gastroresistant [[and/]]or acidoresistant polymer forming a tablet[[, or]];

[[into]] a capsule [[from]]comprising a gastroresistant [[and/]]or acidoresistant polymer[[,]] or

[[into]] an inert capsule which is subsequently coated with a ~~coat from a~~ gastroresistant [[and/]]or acidoresistant polymer.

29. (original) The pharmaceutical dosage form according to claim 28 wherein the dosage form is a tablet comprising microcapsules embedded into a gastroresistant tablet matrix.

30. (currently amended) The pharmaceutical dosage form according to claim 29 where the tablet matrix [[is]]comprises hydroxypropylmethyl cellulose phthalate ~~combination with~~and a mixture of polyvinyl acetate and polyvinylpyrrolidone.

31. (currently amended) The pharmaceutical dosage form according to claim 28 wherein the gastroresistant [[and/]]or acidoresistant polymer is selected from the group consisting of derivatives of methacrylic acid copolymer, hydroxypropylmethyl cellulose phthalate, hydroxyethyl cellulose phthalate, cellulose acetate phthalate, polyvinyl acetyl phthalate, hydroxypropylmethylcellulose acetate succinate [[or]]and combinations thereof.

32. (canceled) A process for the preparation of the pharmaceutical dosage form wherein the dosage form according to any one of claims from 1 to 31 is prepared.

33. (currently amended) A method of treating a chronic inflammatory disease in a human or an animal, the method comprising administering to the human or animal~~Use of a~~ the pharmaceutical dosage form according to claim 1~~any one of claims from 1 to 31 for the preparation of medicament for the treatment of chronic inflammatory diseases in humans or animals~~.

34. (currently amended) The method of claim 33~~Use of a pharmaceutical dosage form according to claim 33~~ wherein the chronic inflammatory disease[[s are]]is selected from the group consisting of colitis, nonspecific ulcerative colitis and Crohn's disease.

35. (canceled) Use of a pharmaceutical dosage form according to any one of claims from 1 to 31 for the treatment of chronic inflammatory diseases in humans or animals.

36. (canceled) Use of a pharmaceutical dosage form according to claim 35 wherein the chronic inflammatory diseases are selected from the group consisting colitis, nonspecific ulcerative colitis and Crohn's disease.